ivoclar vivadent
passion vision innovation

CE 0123

Declaration of conformity

Manufacturer Address	Ivoclar Vivadent AG Bendererstrasse 2 FL – 9494 Schaan Liechtenstein
Product	**IPS Empress® Direct**
Type of material	Light-curing resin-based dental restorative material
Product category	Filling materials
Classification	Medical Device Class IIa

We hereby declare under our exclusive responsibility that the above mentioned products meet the provisions of the following EC Council Directives and its implementation in national law. All supporting documentation is retained on the premises of the manufacturer and the notified body.

Directives	Medical Device Directive 93/42/EEC, Annex II. 3
Notified Body Address	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München Deutschland
Place, Valid from	Schaan, 2014-09-01 Replaces version of: 2014-06-23
Valid until	2019-08-06

Signature		
Name Position	Dr. Thomas Hirt CTO	Dipl. Ing. Patrik Oehri Director CQM and Regulatory Sicherheitsbeauftragter (Product Safety Officer)
Date	2014-09-01	2014-09-01

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Attachment to Declaration of conformity

Product	**IPS Empress® Direct**
Dated	2014-09-01

627217	Empress Direct Cavifil Basic Kit
627218	Empress Direct Basic Kit
627219	Empress Direct Promo Pack
627220	Empress Direct Refill 1x3g A1 Dentin
627221	Empress Direct Refill 1x3g A2 Dentin
627222	Empress Direct Refill 1x3g A3 Dentin
627223	Empress Direct Refill 1x3g A4 Dentin
627224	Empress Direct Refill 1x3g IVA5 Dentin
627225	Empress Direct Refill 1x3g IVA6 Dentin
627226	Empress Direct Refill 1x3g B1 Dentin
627227	Empress Direct Refill 1x3g B2 Dentin
627228	Empress Direct Refill 1x3g C3 Dentin
627229	Empress Direct Refill 1x3g D2 Dentin
627230	Empress Direct Refill 1x3g BL-L Dentin
627231	Empress Direct Refill 1x3g BL-XL Dentin
627232	Empress Direct Refill 1x3g A1 Enamel
627233	Empress Direct Refill 1x3g A2 Enamel
627234	Empress Direct Refill 1x3g A3 Enamel
627235	Empress Direct Refill 1x3g A3.5 Enamel
627236	Empress Direct Refill 1x3g A4 Enamel
627237	Empress Direct Refill 1x3g B1 Enamel
627238	Empress Direct Refill 1x3g B2 Enamel
627239	Empress Direct Refill 1x3g B3 Enamel
627240	Empress Direct Refill 1x3g B4 Enamel
627241	Empress Direct Refill 1x3g C1 Enamel
627242	Empress Direct Refill 1x3g C2 Enamel
627243	Empress Direct Refill 1x3g C3 Enamel
627244	Empress Direct Refill 1x3g D2 Enamel
627245	Empress Direct Refill 1x3g D3 Enamel
627246	Empress Direct Refill 1x3g BL-L Enamel
627247	Empress Direct Refill 1x3g BL-XL Enamel
627248	Empress Direct Refill 1x3g Trans 20
627249	Empress Direct Refill 1x3g Trans 30
627250	Empress Direct Refill 1x3g Opal
627258	Empress Direct Refill 10x0.2g A1 Dentin

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627259	Empress Direct Refill 10x0.2g A2 Dentin
627260	Empress Direct Refill 10x0.2g A3 Dentin
627261	Empress Direct Refill 10x0.2g A4Dentin
627262	Empress Direct Ref. 10x0.2g IVA5 Dentin
627263	Empress Direct Ref. 10x0.2g IVA6 Dentin
627264	Empress Direct Refill 10x0.2g B1Dentin
627265	Empress Direct Refill 10x0.2g B2 Dentin
627266	Empress Direct Refill 10x0.2g C3 Dentin
627267	Empress Direct Refill 10x0.2g D2 Dentin
627268	Empress Direct Ref. 10x0.2g BL-L Dentin
627269	Empress Direct Ref. 10x0.2g BL-XL Dentin
627270	Empress Direct Refill 10x0.2g A1 Enamel
627271	Empress Direct Refill 10x0.2g A2 Enamel
627272	Empress Direct Refill 10x0.2g A3 Enamel
627273	Empress Direct Ref. 10x0.2g A3.5 Enamel
627274	Empress Direct Ref. 10x0.2g A4 Enamel
627275	Empress Direct Ref. 10x0.2g B1 Enamel
627276	Empress Direct Ref. 10x0.2g B2 Enamel
627277	Empress Direct Ref. 10x0.2g B3 Enamel
627278	Empress Direct Ref. 10x0.2g B4 Enamel
627279	Empress Direct Ref. 10x0.2g C1 Enamel
627280	Empress Direct Ref. 10x0.2g C2 Enamel
627281	Empress Direct Ref. 10x0.2g C3 Enamel
627282	Empress Direct Ref. 10x0.2g D2 Enamel
627283	Empress Direct Ref. 10x0.2g D3 Enamel
627284	Empress Direct Ref. 10x0.2g BL-L Enamel
627285	Empress Direct Ref. 10x0.2g BL-XL Enamel
627286	Empress Direct Ref. 10x0.2g Trans 20
627287	Empress Direct Ref. 10x0.2g Trans 30
627288	Empress Direct Refill 10x0.2g Opal
627623	Empress Direct Ref. 10x0.2g A3.5 Dentin
627624	Empress Direct Refill 1x3g A3.5 Dentin
632671	Empress Direct Promo Pack B1
635241	Empress Direct Cav Basic Kit w/o SG EU
635243	Empress Direct Basic Kit without SG EU

Place, Valid from: Schaan, 2016-04-11
Replaces version of: 2014-09-01

Signature		
Name	Dr. Marion Wanner	Sandra Cakebread
Position	Scientific Service, R&D	Regulatory Affairs, R&D
Date	2016-04-11	2016-04-11

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